

ENGINEERING, FACILITIES, AND EQUIPMENT

Biomedical Equipment Maintenance

Year 2000 Effects on Medical Equipment

In the past, when memory was in short supply and very expensive, programs were written with dates represented by only the last two digits of the year (e.g. 95 for 1995). What then seemed like a good way to reduce memory requirements has now resulted in the possibility of major problems with these programs when the year 2000 arrives. The theory is that when the date changes from 31 Dec 99 to 1 Jan 00, the programs will see the 00 as 1900 or some year other than 2000. In addition, it was recently discovered the problem goes much deeper than programming alone, many microchips can not handle the date conversion either. As you would expect, this can wreak havoc in the banking, insurance, and federal benefits industries. But, it may also result in problems with your medical equipment.

Medical equipment most susceptible to the year 2000 (Y2K) effects are those dependent on dates for calculations (e.g. age) or used in conjunction with PCs (either during setup or normal operation). Some equipment that may be affected are radiation treatment planning systems, OR management systems, vital signs monitors, and ECG interpretive programs. Of course, this list is far from complete and items listed may not be affected at all depending on the manufacturer.

The FDA has been soliciting information regarding Y2K from their device reviewers and industry at various conferences for the past six months. The

FDA is preparing a letter to device manufacturers asking them to provide their customers with information regarding the effects of Y2K on their equipment. They estimate this letter will be mailed in approximately six months.

AFMLO, in conjunction with our Army and Navy counterparts, is in the process of surveying the medical equipment industry to determine a list of equipment that will be affected by the Y2K problem and possible solutions. Informal responses indicate many manufacturers are already aware of the problem as it pertains to their equipment, and are taking necessary corrective actions. However, we can not fully depend on manufacturers to take the lead on this issue. We need to be aware a problem may exist with our equipment and take a proactive position towards eliminating the problem.

For those interested in learning more about the cause and possible effects of the year 2000 on information systems, visit the Air Force Y2K Home Page on the internet at:

<http://infosphere.safb.af.mil/~xpsm/frames1.htm>

This is an excellent page that has everything from contract clauses to action plans. For additional information, check out their links, especially the one to the Information Technology Association of American (ITAA) Home Page. ITAA produces a free weekly newsletter on Y2K to subscribe to or read on-line on their home page. The ITAA newsletter covers all sorts of good information including Congressional testimonies and hearings (which is how the medical equipment involvement in this issue came to light).

In addition, we have established a Year 2000 conference forum on the AFMLO Home Page. This forum will be used to post current information on this issue. Also, you should post any information or questions you have to the forum. If you have internet access, regularly check out this site. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

Contract Clause to Ensure Compliance with the Year 2000

To ensure medical equipment you purchase is in compliance with the year 2000 date change, include the attached clause. This clause will hold the contractor responsible for ensuring equipment purchased is compliant with not only the year 2000 date change and multi-century calculations, but also year 2000 leap year calculations.

Provide the following clause to your contracting office when purchasing medical equipment that may use dates in calculations, such as age, or equipment used in conjunction with a PC.

“Date Change Specification for the Year 2000”

“The contractor guarantees the hardware, software, and firmware acquired by the government prior to, during, or after calendar year 2000, shall include design and/or performance specifications to ensure the government shall not experience performance abnormalities associated with calculations for the Year 2000. The design to ensure year 2000 compatibility shall include, but not be limited to, date/century recognition, calculations that accommodate same century and multi-century formulas and date values, and date data interface values that reflect an accurate and correct day, month, year and century. In the manipulation of external data, the contractor is responsible for ensuring the system works accurately based on correct data input. When a total system is contracted for, the contractor is responsible for ensuring that calculations are accurate and successful in computations involving the year 2000. In addition, the contractor guarantees that the year 2000 leap year calculations will be accommodated and will not result in hardware, firmware, and/or software failures. The prime contractor is

responsible for their subcontractor’s products and services provided under this contract.” (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

Marquette Medical Systems Responds to the Year 2000 Issue

Marquette Medical Systems recently provided AFMLO an official response to how their equipment is affected by the year 2000. The letter states that “all of Marquette’s equipment manufactured this decade has been designed with a four-digit date field” and therefore will not be affected by the year 2000 date change.

However, Marquette equipment manufactured prior to 1990 may have some problems with the date conversion. “Corometrics monitors, models 145 and 220, are incapable of handling the date change.” Also, the DEC-based MUSE (our CAPOC system) “is incapable of being upgraded to accept the date change.”

“The diagnostic cardiology carts are a bit more complicated” and some of the earlier ECG carts (Mac 10, Mac 12, and Mac 15) will require a software upgrade. All of the more recent carts (MacPC and later) are already running enhanced software that handles the date change. Marquette has not yet determined how software upgrades for the earlier ECG carts will be distributed.

All other Marquette equipment not mentioned above is assumed to be year 2000 compliant. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

Update to Air Transportable Clinic (ATC) (3kW) Generator Instructions

Attachment 1, page 10, contains new instructions for establishing uniform generator electrical installation for ATCs (3kW). Cables modified based on instructions printed in AFMLL 04-96 do not require additional modification. Thanks to A1C Scott Woods at Fairchild AFB WA for suggesting this alternate method resulting in a savings of \$390 per ATC.

Implementation of this suggestion is optional and the specific benefits should be evaluated locally by each base. If your facility adopts this suggestion, complete AF Form 1000-1, Suggestion Evaluation and Transmittal, citing the suggestion number (FAI960108), and forward it to the originating base suggestion program office (92ARW/MO, 8 South Olympia, Suite 128, Fairchild AFB WA 99011-9500). (AFMLO/FOM-E, Mr. David Baker, DSN 343-7487)

Facilities Management

Registration for the 1997 Joint Services Medical Facilities Management Symposium (JSMFMS)

The Joint Services Medical Facilities Management Symposium (JSMFMS) will be held 14-18 July 1997 in San Antonio, Texas. Detailed registration procedures and symposium information are contained in **Attachment 1**, pages 3 through 9. If you have questions, contact Ms. Teri Baal at (301) 619-4182 or DSN 343-4182. (AFMLO/FOM-F, Capt Rhonda Hillman, DSN 343-2117)

Quality Assurance

Food and Drug Administration (FDA) Recalls/Alert Notices

Attachment 2, paragraph 1, provides information on FDA medical equipment recalls and alerts. Personnel from clinical engineering, biomedical equipment maintenance, quality assurance, and safety should follow the guidance provided to ensure the effective maintenance and management of medical equipment. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

Safety Alerts

Batteries, Medical Device, MDC 16337, 3.5 Volt NiCad Batteries used with Nicator S 3.5 Volt Fiberoptic Laryngoscopes, Heine USA Ltd.

Reference ECRI *Health Devices Alerts* Number 1997-A11, 14 March 1997, Accession No. A3215. ECRI reports that a distributor reported that the labels on the batteries used with the above laryngoscopes may have the insertion directions reversed, and may cause the unit to short circuit if the battery is inserted incorrectly. This short circuit can cause the battery wrapping to melt and smoke and the laryngoscope handle to become warm to the touch. Heine USA Ltd initiated a field correction by letter dated 4 March 1997, to its distributors, instructing them to exchange the affected batteries with new ones equipped with friction disks. Service representatives will arrange to visit customers with affected units and replace the batteries with ones that have a friction disk as well as a poly-switch that acts as a fuse for the battery. For further information, contact Andy Floyd, Heine USA Ltd at (800) 367-4872.

Physiologic Monitoring Systems, Acute Care, MDC 12647, DINAMAP Vital Signs Monitors: (1) Series 8100, (2) Series 8700, (3) Series 9300, (4) Series 9700, Johnson & Johnson Medical Inc.

Reference ECRI *Health Devices Alerts* Number 1997-A11, 14 March 1997, Accession No. A3219. ECRI reports that a member hospital reported the intermittent disconnection of line cords on DINAMAP Vital Signs monitors. Although the units appeared to be plugged in, the units indicated that they were operating on battery power rather than line power. The detachable power cords were not securely plugged into the units, resulting in loss of electrical contact between the cord and the device. The units did not have power cord retention clips attached. ECRI states that unsecured detachable power cords can come loose when a device is moved, when someone trips over or pulls on the cord, or when the cord is not properly reinserted after being removed. The manufacturer (J&J) states that the 8100 Series monitors have been replaced by the DINAMAP XL monitors (9300 Series), which are shipped with a power cord retention clip that can be installed upon receipt. Current users of 8100, 8700, and 9700 Series monitors can request retention clips for those units (Part No. PBR 300-857) free of charge by contacting their J&J sales representative or by calling J&J at (800) 255-2500. ECRI recommends that retention clips are installed and checked during routine inspections and that users are trained to keep the retention clip engaged at all times.

MECTA Model C Electroconvulsive Therapy Units, MECTA Corporation

MECTA Corporation issued a letter stating that effective 1 July 1997, they will no longer be able to provide parts and service for MECTA Model C units. Model C units were last produced in 1981.

MECTA Corporation will offer, with the trade-in of a Model C unit, \$1000.00 against the purchase price of any MECTA SR/JR unit until 1 July 1997. The following parts for Model C units will be available until 1 July 1997, or until they are sold out, whichever occurs first.

<u>Description</u>	<u>Part Number</u>	<u>Price</u>
Allen Wrench 5/64"	9016-0001	\$0.55
Chart Paper	9252-0501	\$15.00
Light Bulb	9150-0004	\$2.00
Pt Monitor Cable	9010-0005	\$36.00
Pt Stimulus Cable	9438-0083	\$27.00

MECTA Corporation can be contacted at (503) 624-8778. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

Product Correction -- Vital Signs Monitors, MDC 17678, Propaq Encore Monitors, Protocol Systems, Inc.

Protocol Systems, Inc., sent a letter dated 7 March 1997, to all known customers stating they will perform a field correction on Propaq Encore monitors with serial numbers between DA003829 and DA005650 as well as some monitors serviced during 1996. The letter states that a malfunctioning component on the recharger board can cause the fuses to fail in the monitor and/or in the external power adapter. If this occurs, the green charging light on the monitor fails to illuminate. The monitor will continue to run normally until the battery is depleted. As battery voltage drops, the monitor's alarms will activate indicating that the monitor is not charging. Protocol Systems is conducting a product correction of all affected instruments in an effort to prevent malfunctions. A Protocol representative will contact using activities to arrange service for the affected monitors. Using activities should ensure that they have received the 7 March 1997

letter from the manufacturer and coordinate the field correction. For further information or to request a copy of the letter, contact Protocol Systems by phone at (800) 289-2501 or (503) 526-8500, or e-mail to:

solutions@protocol.com

(AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

Medical Equipment Management

Shared Procurement Equipment Items Currently Available

Attachment 1, pages 1 and 2, contains a list of all current Shared Procurement contracts and optional contracts available through the Defense Personnel Support Center (DPSC). If you plan to order any of these items for your facility, use the specific ordering instructions and overall program guidance contained in AFMLL 04-96, pages CE-4 and CE-5. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

“Piggyback” Contracts Currently Available

AFMLL 16-96, Attachment 1, pages 4 and 5, contains a list of all current “piggyback” contracts currently available through DPSC. These contracts

will allow facilities to “piggyback” requirements onto existing orders placed for specific quantities. Many of these contracts are designed to buy large quantities at reduced prices, and are written with the option of buying additional quantities at the same price. The list includes available quantities and “Order By” dates. To order, send your MILSTRIP requisitions to DPSC, and reference the contract number (from the listing) in the notes section. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

WILLIAM H. HILL

Deputy Chief, Air Force Medical Logistics Office